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Customer Number 22,852

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Robert Frederick VEASEY et al.) Group Art Unit: 3736
)
Application No.: 10/790,026) Examiner: Not Yet Assigned
)
Filed: March 2, 2004) Confirmation No.: 9739
)
For: IMPROVEMENTS IN AND)
RELATING TO DRIVE)
MECHANISMS SUITABLE FOR)
USE IN DRUG DELIVERY)
DEVICES)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CLAIM FOR PRIORITY

Under the provisions of 35 U.S.C. § 119, Applicants hereby claim the benefit of the filing date of March 3, 2003, British Patent Application No. GB0304824.6, filed March 3, 2003, for the above-identified U.S. patent application.

In support of this claim for priority, enclosed is one certified copy of the priority application.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 19, 2004

By: Elizabeth M. Burke
Elizabeth M. Burke
Reg. No. 38,758

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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears a correction, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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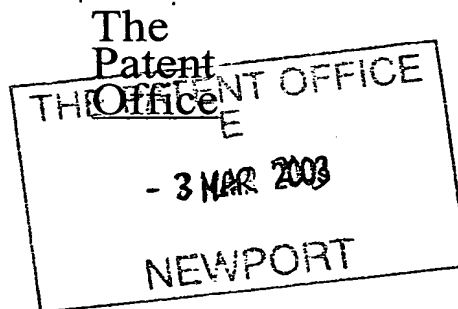
Andrew C. Carey

Dated 17 June 2004

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Patent Form 1/77.

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1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

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04MAR03 E789261-5 000351

P0177700 0.00-0304824.6

1.	Your reference	JAM/P96028UK		
2.	Patent application number (The Patent Office will fill in this part)	03 MAR 2003	0304824.6	
3.	Full name, address and postcode of the or of each applicant (underline all surnames)	DESKIN DCA International Limited 19 Church Street Warwick CV34 4AB		
	Patents ADP number (if you know it)	16.609 8578 004001 07673684000		
	If the applicant is a corporate body, give the country/state of its incorporation			
4.	Title of the invention	Improvements in and relating to a pen-type injector		
5.	Name of your agent (if you have one)	Lewis & Taylor		
	"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	5 The Quadrant Coventry CV1 2EL		
	Patents ADP number (if you know it)	711001		
6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and (if you know it) the or each application number	Country	Priority application number (if you know it)	Date of filing (day / month / year)
7.	If this application is divided or otherwise derived from an earlier UK application, give the number and filing date of the earlier application	Number of earlier application	Date of filing (day / month / year)	
8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'yes' if: a) any applicant named in part 3 is not an inventor, or b) there is an inventor who is not named as an applicant, or c) any named applicant is a corporate body.			

9. For the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description	10
Claim(s)	3
Abstract	-
Drawing(s)	3 ^{x2}

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translation of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*) ☒

Request for substantive examination (*Patents Form 10/77*)

Any other documents
(please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

John A Moffat

Date

3 March 2003

12. Name and daytime telephone number of person to contact in the United Kingdom
- J A Moffat
(024) 7622 2756/7145

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Improvements in and relating to a pen-type injector

The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose
5 cartridge. In particular, the present invention relates to such injectors where a dose may be set by a user.

Such injectors have application where regular injection by persons without formal medical training occurs. This is increasingly common amongst those having
10 diabetes where self-treatment enables such persons to conduct effective management of their diabetes.

These circumstances set a number of requirements for pen-type injectors of this kind. The injector must be robust in construction, yet easy to use both in terms of
15 the manipulation of the parts and understanding of its operation. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision. Where the injector is to be disposable rather than reusable, the injector should be cheap to manufacture and easy to dispose of (preferably being suitable for recycling).

20 It is an advantage of the present invention that an improved pen-type injector is provided.

According to a first aspect of the present invention, a pen-type injector a housing;
25 a dose dial sleeve having a dose dial thread of first lead; and a piston rod; characterised in that the piston rod comprises an outer part having an external thread of second lead and an inner part having an external thread of third lead, the first lead of the dose dial thread being equal to the sum of the second lead of the outer part of the
30 piston rod and the third lead of the inner part of the piston rod.

Preferably the dose dial sleeve is connected to the housing for rotation with respect thereto;

the outer part of the piston is adapted for longitudinal displacement only with respect to the housing;

- 5 ratchet means prevent rotation between the outer part of the piston rod and the housing;

clutch means adapted to act between the dose dial sleeve and the piston rod; a drive sleeve is provided releasably connected to the dose dial sleeve and is also connected to the piston rod for rotation with respect thereto;

- 10 a button located on the dose dial sleeve and rotatable with respect to the dose dial sleeve; and in which
the clutch means upon depression of the button engages to prevent rotation between the dose dial sleeve and the piston rod.

- 15 Preferably, the clutch means acts between the dose dial sleeve and the inner part of the piston rod.

Preferably, the inner part and the outer part of the piston rod are adapted for longitudinal displacement but are restricted for rotation with respect to one
20 another.

Preferably, the housing and the dose dial sleeve are provided with interengaging features to provide a helical thread between the housing and the dose dial sleeve.

25

Preferably, the dose dial sleeve comprises a first section of first diameter and a second section of second diameter, the helical thread being formed between an outer surface of the first section of the dose dial sleeve and the housing.

- 30 Preferably, the drive sleeve comprises a helical groove along an internal surface extending from a first end of the drive sleeve towards an internal land, the land being further provided with a radially inwardly directed flange.

Preferably, clicker means are provided between the clutch means and the dose dial sleeve, the clicker means comprising an insert having an upper part and a lower part depending therefrom, the upper part of the insert is provided on an internal surface with a plurality of circumferentially spaced longitudinally extending teeth, the lower part of the insert comprising a flexible toothed member being disposed in alignment with a plurality of circumferentially disposed longitudinally directed teeth provided on an inner surface of the dose dial sleeve, and the inner surface of the upper part of the insert having a plurality of circumferentially disposed longitudinally extending teeth being disposed in alignment with a flexible toothed member provided on the clutch means such that relative rotation between the dose dial sleeve and the clutch means causes one of the flexible toothed members to ride over corresponding longitudinally directed teeth to produce a series of clicks.

Preferably, the ratchet means are in the form of barbs or tangs extending from the housing.

Preferably, the clutch means comprises a plurality of radially extending longitudinally directed teeth provided respectively on the dose dial sleeve and a disc connected to the inner part of the piston rod.

The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:-

Figure 1 shows a sectional side view of an injector in accordance with the present invention in a first position;

Figure 2 shows a sectional side view of the injector of Figure 1 in a second position;

Figure 3 shows a sectional side view of the injector of Figure 1 in a third position;

Figure 4 shows a sectional side view of the injector of Figure 1 in a fourth position; and

Figure 5 shows a sectional side view of the injector of Figure 1 in a final position.

Referring first to Figure 1 there may be seen an injector in accordance with the present invention. The injector comprises a housing 2 within which are located a cartridge 4 containing a medicinal product, means for selecting or setting of the dose of medicinal product to be expelled and means for expelling the selected dose of medicinal product. The housing 2 is generally cylindrical in shape and is divided into two compartments by a web 6 to be described in more detail below. The cartridge 4 is located within a first part of the housing 2 while the dose setting means and the means for expelling the selected dose of medicinal product are located within a second part of the housing 2.

The cartridge 4 may be secured in position in the first part of the housing 2 by any suitable means. In the illustrated embodiment, a cartridge retainer 12 is secured, by any suitable means, to a first side of the web to retain the cartridge in position. A needle unit (not shown) may be secured to a first end of the cartridge retainer 12. The cartridge 4 further comprises a displaceable piston 10. Advancing the piston 10 towards the first end of the cartridge 4 causes the medicinal product to be expelled from the cartridge 4 through the needle unit. A cap may be provided to cover the needle unit when the injector is not in use.

The web 6 dividing the housing 2 extends radially inwards from the cylindrical housing to define an opening 8. A piston rod 14 extends through the opening 8 in the web 6. The piston rod 14 comprises a first inner part 16 and a second outer part 18. The inner part 16 and the outer part 18 of the piston rod are keyed or ratcheted by a one-way ratchet to one another for longitudinal displacement therebetween such that rotation between the inner and outer parts of the piston rod 14 is restrained in a first direction. In the illustrated embodiment, the inner part 16 is keyed to the outer part 18 by at least one radially extending flexible barb 17 extending from the inner part 16 that runs in longitudinally extending grooves 19 on an inner surface of the outer part 18 of the piston rod 14. In the illustrated embodiment, two diametrically opposed flexible barbs 17 are used, only one of which may be seen in each view, the other being hidden.

The first inner part 16 of the piston rod 14 is provided along a second end with a threaded portion 22. The second outer part 18 of the piston rod 14 is provided along a second end with a helical rib 24 on an outer surface thereof.

5

Ratchet means 20 are provided in the form of a number of barbs or tangs extending from the housing. The ratchet means 20 prevents relative rotation between the outer part 18 of the piston rod 14 and the housing 2. The ratchet means 20 also prevents the outer part 18 of the piston rod 14 from retracting counterwise back into the main housing 4, that is away from the cartridge piston 10.

10

The dose setting means and the means for expelling the selected dose of medicinal product will now be described in more detail.

15

A drive sleeve 30 is located at a second end of the piston rod 14. The drive sleeve 30 is cylindrical. A helical groove 32 extends along an internal surface of the drive sleeve 30 from a first end of the drive sleeve 30 towards an internal land 34. The land 34 is further provided with a second thread 36 for engagement with the threaded portion 22 on the inner part 16 of the piston rod 14.

20

The helical groove 32 and the helical rib 24 engage to permit relative rotation between the outer part 18 of the piston rod 14 and the drive sleeve 30. The second thread 36 runs in the threaded portion 22 of the inner part 16 of the piston rod 14 to permit relative rotation between the drive sleeve 30 and the inner part 16 of the piston rod 14.

25

The helical rib 24 and second thread 36 are opposite handed.

30

A dose dial sleeve 40 is of generally cylindrical form and comprises a first section of first diameter and a second section of second diameter. The first section is disposed between the drive sleeve 30 and the housing 2. An outer surface of the

first section and an inner surface of the housing 2 are provided with interengaging features to provide a helical thread 46 between the housing 2 and the dose dial sleeve 40. This enables the dose dial sleeve 40 to rotate about and along the housing 2. Conveniently, the outer surface of the dose dial sleeve 40 is provided with numerals or other indications (not shown) of the possible doses to be dialled. Preferably, the housing is provided with a window (not shown) through which a numeral or other indication representative of the user's chosen dosage is displayed.

10 The inner surface of the dose dial sleeve 40 and the outer surface of the drive sleeve 30 are keyed together to permit only longitudinal displacement therebetween. Conveniently, the dose dial sleeve 40 and the drive sleeve 30 are splined together.

15 The second section of the dose dial sleeve 40 is preferably of the same outer diameter as the housing 2. Within the dose dial sleeve 40 there is a shoulder 42 between the first section of the dose dial sleeve 40 and the second section of the dose dial sleeve 40. An internal surface of the shoulder 42 is provided with a plurality of radially extending longitudinally directed teeth. An internal surface of the second section of the dose dial sleeve 40 is provided with a plurality of circumferentially spaced longitudinally extending saw teeth 54. Each of the saw teeth has a radially directed surface and an inclined surface.

25 The second section of the dose dial sleeve 40 comprises a first recessed region in which is retained a clutch means 48 and a further region in which a button 50 is retained. The button 50 is free to rotate within the second section of the dose dial sleeve 40 and is axially connected to the clutch means 48. The button 50 is of generally "T" shaped configuration, the stem of which is retained within a peripheral recess provided in the clutch means 48. The stem of the button 50 is provided with a peripheral bead that is retained in the peripheral recess, the button 50 being able freely to rotate with respect to the clutch means and the dose dial sleeve 40, but being retained axially within the clutch means 48.

Conveniently, the clutch means includes a disc having a plurality of radially extending longitudinally directed teeth. The clutch means 48 are retained on the first inner part 16 of the piston rod 14 such that there is no relative rotation therebetween. When the dose dial sleeve 40 and the clutch means 48 are not forced together the respective teeth will ride over one another. Preferably, the radial separation of the respective teeth corresponds to a unit dosage. The clutch means 48 are connected to the inner part 16 of the piston rod 14 such that relative rotation therebetween is prevented.

Clicker means are also provided between the clutch means 48 and the second section of the dose dial sleeve 40. In the illustrated embodiment, the second section of the dose dial sleeve 40 is provided with an insert 44 having an upper part and a lower part depending therefrom. The upper part of the insert 44 is provided on an internal surface with a plurality of circumferentially spaced longitudinally extending saw teeth. Each of the saw teeth has a radially directed surface and an inclined surface. The clutch means 48 carries a flexible toothed member 52 about an upper region of the clutch means 48 aligned with the upper part of the insert 44.

The lower part of the insert 44 is in the form of a flexible toothed member normally biased in a radially outward direction. The lower part of the insert 44 is normally aligned with the teeth 54 provided on the internal surface of the second section of the dose dial sleeve 40.

The radial separation of the teeth on each of the dose dial sleeve 40 and the insert 44 preferably corresponds to a unit dosage.

Relative rotation between the dose dial sleeve 40 and the clutch means 48 in a first direction will cause the flexible toothed member 52 to ride over the inclined surfaces of the saw teeth on the insert 44 to produce a series of clicks.

Conversely, relative rotation between the dose dial sleeve 40 and the clutch

means 48 in a second direction opposite to the first direction will cause the flexible toothed member 52 to abut the radial surface of one of the saw teeth of the upper part of the insert and push the insert 44 in the second direction.

5 However the lower part of the insert 44 is then caused to ride over the inclined surfaces of the saw teeth 54 on the dose dial sleeve 40 to produce a series of clicks.

The first direction may be selected to represent an upward or downward dialling of a dose, the second direction the converse dialling condition subject to a
10 suitable arrangement of the flexible members and longitudinally extending teeth.

In Figure 1, the injector is provided with a prefilled cartridge 4. To operate the injector a user must first select a dose. To set a dose the second section of the dose dial sleeve 40 is rotated with respect to the housing 2 outward from the
15 housing 2. Since the drive sleeve 30 cannot rotate with respect to the dose dial sleeve 40, this is rotated out from an initial position by an amount corresponding to the desired dosage. The drive sleeve 30 is thus rotated about the helical rib 24 of the outer part 18 of the piston rod. The second thread 36 of the drive sleeve 30 thus also runs in the threaded portion 22 of the inner part 16 of the
20 piston rod 14 drawing the inner part 16 of the piston rod 14 from the outer part 18 by a distance a function of the dosage chosen by a user. When a dose is dialled, the drive sleeve 30 descends on an inner part 16 of the piston rod a distance equal to the distance required to displace the cartridge piston 10 to expel the selected dose of medical product.

25

In the illustrated embodiment, on dialling up of a dose the relative rotation between the dose dial sleeve 40 and the clutch means 48 (fixed rotationally with respect to the inner part 16 of the piston rod 14) causes the flexible toothed member 52 to ride over the teeth 54 on the dose dial sleeve 40 to create a series
30 of clicks. This is an audible confirmation of the dose being dialled. On dialling down, the insert 44 is locked to the dose dial, and the flexible member 52 acts on

the teeth of insert 44. In this way an audible confirmation of the dialling action of a user is produced.

5 The user may rotate the dose dial sleeve 40 to increase or decrease the amount of the dosage selected to be delivered. Conveniently, the first section of the dose dial sleeve 40 is provided with a marked scale, which together with associated features of the housing, enable a user to determine the amount of the dosage selected to be delivered. The associated features of the housing 2 may include a window formed in the housing 2 or a marking on the housing 2 for alignment with
10 the marked scale.

Once a desired dose has been set (as shown for example in Figure 2), to deliver the dose the user depresses the button 50 to urge the button 50 and associated clutch means 48 towards the first end of the housing 2. When the button 50 is
15 depressed the clutch means 48 is driven into the second section of the dose dial sleeve 40 to prevent relative rotation between the dose dial sleeve 40 and the inner part 16 of the piston rod 14. The drive sleeve 30 may still rotate with respect to the button 50. Further longitudinal movement of the button 50 causes the dose dial sleeve 30 (together with the drive sleeve 40) to rotate towards the
20 first end of the injector. As the dose dial sleeve 40 travels into the housing 2, rotation of the drive sleeve 30 (keyed to the dose dial sleeve 40) forces the outer part 18 of the piston rod 14 to move axially with respect to the housing 2.

Rotation of the inner part 16 of the piston rod 14 within the outer part 18 of the
25 piston rod 14 as the button is advanced towards the first end of the housing 2 causes the barb 17 to run across the grooves 19 to provide tactile and audible feedback as each unit of medicinal product is dispensed. It may be seen that preferably, the angular spacing of the grooves 19 preferably corresponds to a unit dose.

30 The outer part 18 of the piston rod 14 continues to advance until the dose dial sleeve 40 has returned to the initial position in relation to the housing and the

drive sleeve has returned to its initial position in relation to the outer part 18 of the piston rod 14 (Figure 3).

Further dosages may be delivered as required. Figure 4 shows an example of a subsequently selected dosage. It will be noted that the drive sleeve 30 has advanced further along the threaded portion 22 of the inner part 16 of the piston rod 14. The position of the drive sleeve 30 along the threaded portion 22 corresponds to the amount of medicinal product remaining in the cartridge 4, such that when the drive sleeve 30 reaches the end of the threaded portion 22 and can rotate no further this corresponds to no medicinal product remaining in the cartridge 4. It will be seen that if a user seeks to select a quantity of medical product greater than that remaining in the cartridge 4, this cannot be done since when the drive sleeve 30 stops rotating this prevents further rotation of the dose dial sleeve 40 and setting of a larger dose.

Figure 5 shows an injector according to the present invention in which the entire medical product within the cartridge 4 has been expelled.

CLAIMS

1 A pen-type injector comprising a housing;

a dose dial sleeve having a dose dial thread of first lead; and

5 a piston rod; characterised in that

the piston rod comprises an outer part having an external thread of second lead and an inner part having an external thread of third lead, the first lead of the dose dial thread being equal to the sum of the second lead of the outer part of the piston rod and the third lead of the inner part of the piston rod.

10

2 An injector according to claim 1, characterised in that the dose dial sleeve connected to the housing for rotation with respect thereto;

the outer part of the piston is adapted for longitudinal displacement only with respect to the housing;

15 ratchet means prevent rotation between the outer part of the piston rod and the housing;

clutch means adapted to act between the dose dial sleeve and the piston rod;

a drive sleeve is provided releasably connected to the dose dial sleeve and is also connected to the piston rod for rotation with respect thereto;

20 a button located on the dose dial sleeve and rotatable with respect to the dose dial sleeve; and in which

the clutch means upon depression of the button engages to prevent rotation between the dose dial sleeve and the piston rod.

25 3 An injector according to claim 2, characterised in that the clutch means acts between the dose dial sleeve and the inner part of the piston rod.

4 An injector according to any previous claim, characterised in that the inner part and the outer part of the piston rod are adapted for longitudinal displacement

30 but are restricted for rotation with respect to one another.

5 5 An injector according to any previous claim, characterised in that the housing and the dose dial sleeve are provided with interengaging features to provide a helical thread between the housing and the dose dial sleeve.

5 6 An injector according to claim 5, characterised in that the dose dial sleeve comprises a first section of first diameter and a second section of second diameter, the helical thread being formed between an outer surface of the first section of the dose dial sleeve and the housing.

10 7 An injector according to any of claims 2 to 6, characterised in that the drive sleeve comprises a helical groove along an internal surface extending from a first end of the drive sleeve towards an internal land, the land being further provided with a radially inwardly directed flange.

15 8 An injector according to any of claims 2 to 7, characterised in that clicker means are provided between the clutch means and the dose dial sleeve, the clicker means comprising an insert having an upper part and a lower part depending therefrom, the upper part of the insert is provided on an internal surface with a plurality of circumferentially spaced longitudinally extending teeth,
20 the lower part of the insert comprising a flexible toothed member being disposed in alignment with a plurality of circumferentially disposed longitudinally directed teeth provided on an inner surface of the dose dial sleeve, and the inner surface of the upper part of the insert having a plurality of circumferentially disposed longitudinally extending teeth being disposed in alignment with a flexible toothed
25 member provided on the clutch means such that relative rotation between the dose dial sleeve and the clutch means causes one of the flexible toothed members to ride over corresponding longitudinally directed teeth to produce a series of clicks.

30 9 An injector according to any of claims 2 to 8, characterised in that the ratchet means are in the form of barbs or tangs extending from the housing.

10 An injector according to any of claims 2 to 9, characterised in that the clutch means comprises a plurality of radially extending longitudinally directed teeth provided respectively on the dose dial sleeve and a disc connected to the inner part of the piston rod.

5

11 An injector substantially as described herein with reference to and as illustrated in the accompanying drawings.

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Fig 2

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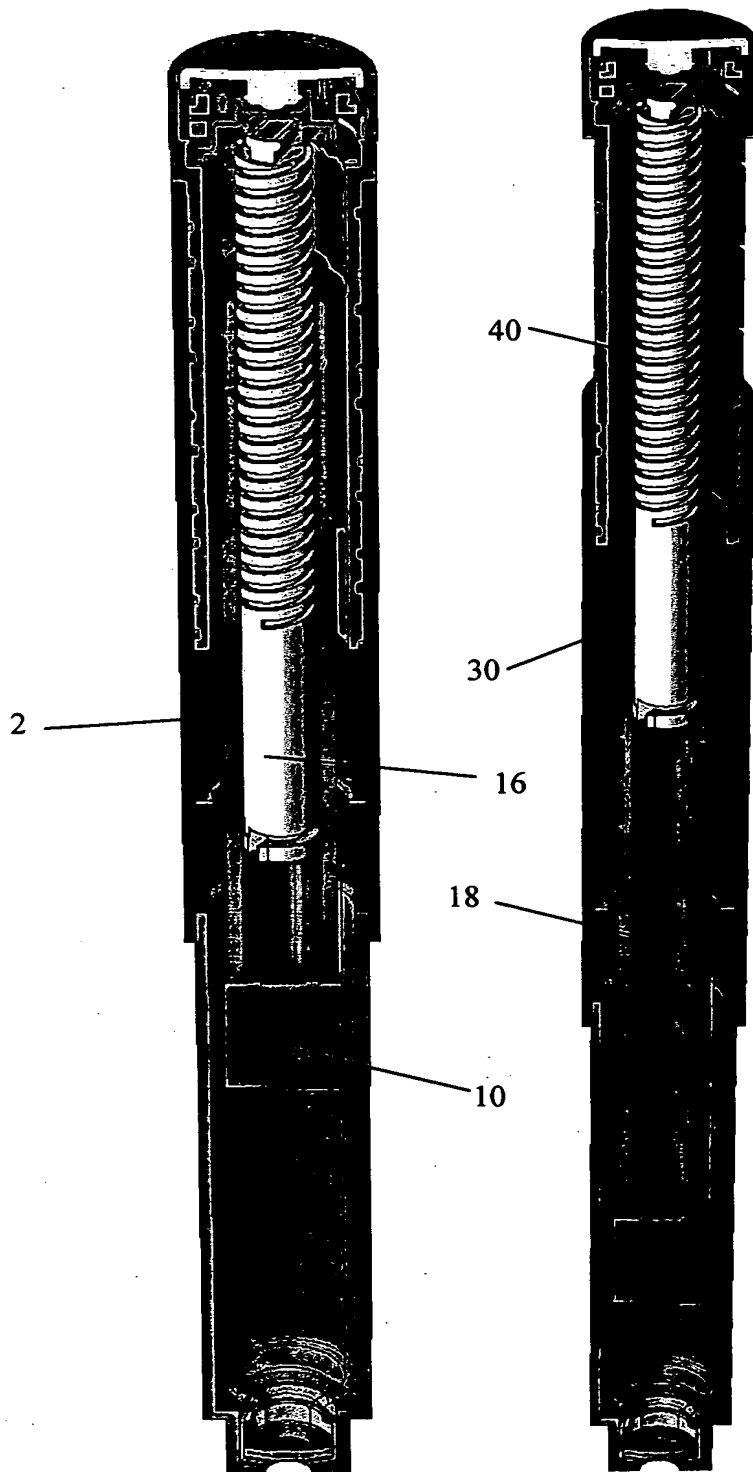


Fig 3

Fig 4

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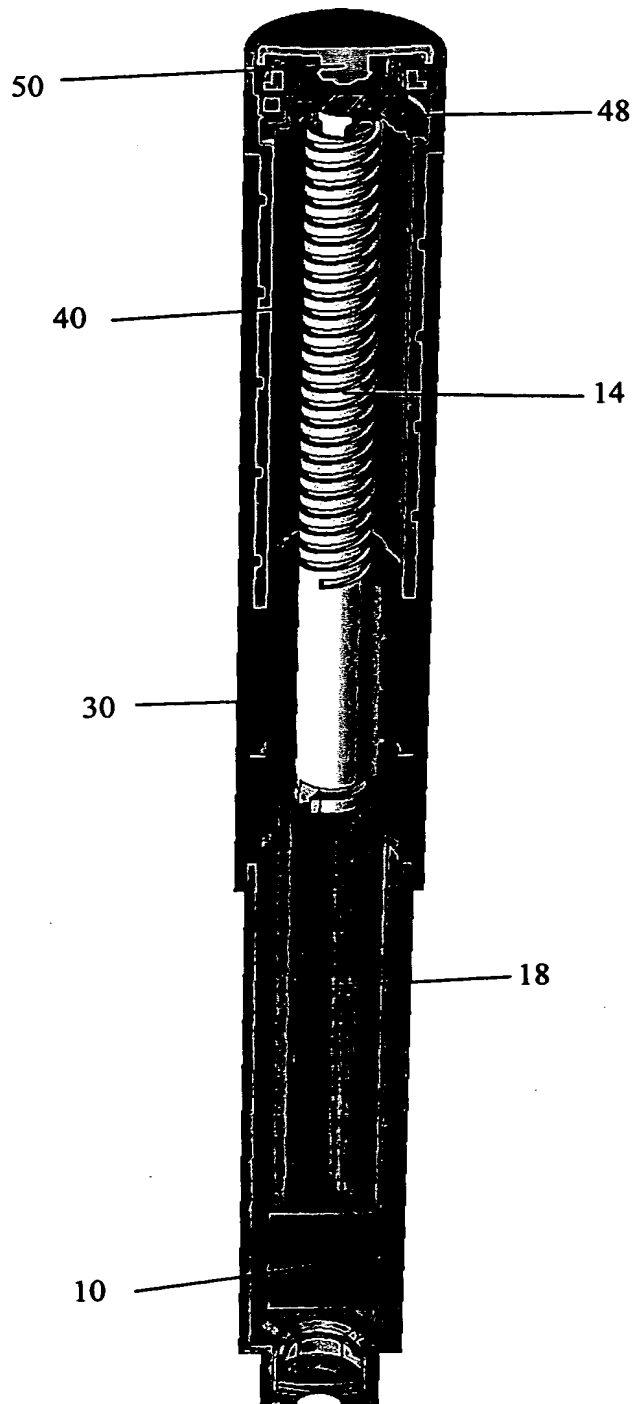


Fig 5

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